

scientific device manufacturer, L.L.C.

OCT 29 1996

999 Andersen Drive, Suite 120
San Rafael, California 94901
Phone 415-454-9370 Fax 415-454-9380

SUMMARY OF SAFETY AND EFFECTIVENESS

K960431

SDM Angiographic Manifold with Extension Lines

510(k) Premarket Notification

Trade Name: SDM Angiographic Manifold

Generic Name: Stopcock and Manifold

Manufacturer: Scientific Device Manufacturer, LLC.
999 Andersen Drive, Suite 110
San Rafael, CA 94901
Establishment Registration Number: TBD

Classification:

In preparation of this PreMarket Notification, it was determined that devices of this generic type have been previously classified as Class II devices. No performance standards have yet been established for these products.

Product Description:

The SDM Angiographic Manifold consists of one or more stopcocks, where the multiple stopcock configurations are connected in line to form a manifold, with some models of each also having a high pressure extension line attached. These devices have bodies made of polycarbonate and handle plugs made of polyethylene. The plugs are lightly siliconized for smooth rotation. Each of the devices will be supplied single packaged and sterile. Packaging will consist of a standard Tyvek/Poly pouch.

Intended Use:

This device provides additional access ports into a standard angiographic fluid delivery system and can be used in conjunction with syringes and other accessories where angiographic injection is indicated. This product's medium/high pressure designation does not preclude its use for low pressure modalities.

Rationale for Substantial Equivalence:

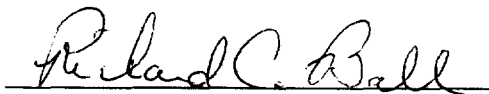
Scientific Device Manufacturer's Stopcock / Manifolds are substantially equivalent to currently marketed medium and high pressure stopcock / manifold devices with regards to intended use, materials, and design. Dimensions, materials, and functionality have been chosen to replicate several of the predicate devices, including those made by Namic, Medex, and Spectra Medical. No significant changes or modifications were made from those devices. SDM therefore posits that its devices are equivalent in safety and effectiveness to those devices.

Biocompatibility Evaluation:

Materials used in Scientific Device Manufacturer's Angiographic Manifolds were chosen to be generically the same as those present in the substantially equivalent devices. Testing performed by SDM for this externally communicating device (blood path indirect) shows this device to be biocompatible per the requirements of ISO Standard 10993, Part I.

Summary:

Based upon the product description, its intended use, and comparative features of predicate devices, the Scientific Device Manufacturer's Angiographic Manifold is substantially equivalent to other medium and high pressure manifolds currently in use.


Richard C. Ball

Vice President Regulatory Affairs and Quality Assurance